

BASALOG[®]

Insulin Glargine Injection (rDNA origin) 100 IU/mL

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1) What BASALOG[®] is used for

BASALOG[®] (insulin glargine [recombinant DNA origin]) is long-acting insulin.

Because BASALOG[®] is made by recombinant DNA (rDNA) technology and is chemically different from the insulin made by the human body; it is called an insulin analog. BASALOG[®] is used to reduce high blood sugar in adults, adolescents and children of 2 years or above with diabetes mellitus. Diabetes mellitus is a condition in which a person has high blood sugar, either because the pancreas does not produce enough insulin or the cells do not respond to the insulin that is produced. Extra insulin is therefore needed to lower your blood sugar level after the injection. Insulin glargine has a long and steady blood-sugar-lowering action.

2) How BASALOG[®] works

Insulin glargine is a human insulin analogue designed to have low solubility at a neutral pH. It is completely soluble at the acidic pH of the injection solution (pH 4). After injection into subcutaneous tissue, the acidic solution is neutralised leading to formation of micro-precipitates from which small amounts of insulin glargine are continuously released, providing a smooth, peakless, predictable concentration/time profile with a prolonged duration of action.

3) Before you use BASALOG[®]

When you must not use it

- If you are allergic (hypersensitive) to insulin glargine or any of the other ingredients of BASALOG[®]. (see section 8 for a full list of ingredients). Watch out for the signs of allergy in section 6 (side effects) or ask your doctor for clarification.
- If you experience symptoms of low blood sugar levels (hypoglycaemia), or a hypoglycaemic attack (symptom of low blood sugar) coming on. See section 5 (while you are using it) or to know more about hypoglycaemia

Before you start to use it

- If you have Medical conditions: medical conditions can alter your insulin requirements. Consult your doctor for a change in dose.

Taking other medicines

Some medicines cause changes in the blood sugar level (decrease, increase or both depending on the situation). In each case, it may be necessary to adjust your insulin dose to avoid blood sugar levels that are too low or too high. Be careful when you start or stop taking another medicine. Please tell your health care provider (doctor, nurse, or pharmacist) if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Before taking a medicine ask your doctor if it can affect your blood sugar level and what action, if any, you need to take.

Medicines that may cause your blood sugar level to fall (hypoglycaemia) include:

All other medicines to treat diabetes, angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure), disopyramide (used to treat certain heart conditions), fluoxetine (used to treat depression), fibrates (used to lower high levels of blood lipids), monoamine oxidase (MAO) inhibitors (used to treat depression),

pentoxifylline, propoxyphene, salicylates (such as aspirin, used to relieve pain and lower fever), sulfonamide antibiotics.

Medicines that may cause your blood sugar level to rise (hyperglycaemia) include: corticosteroids (such as "cortisone", used to treat inflammation), danazol (medicine acting on ovulation), diazoxide (used to treat high blood pressure), diuretics (used to treat high blood pressure or excessive fluid retention), glucagon (pancreas hormone used to treat severe hypoglycaemia), isoniazid (used to treat tuberculosis) oestrogens and progestogens (such as in the contraceptive pill used for birth control), phenothiazine derivatives (used to treat psychiatric disorders), somatropin (growth hormone), sympathomimetic medicines (such as epinephrine [adrenaline], or salbutamol, terbutaline used to treat asthma), thyroid hormones (used to treat thyroid gland disorders), atypical antipsychotic medicines (such as clozapine, olanzapine), protease inhibitors (used to treat HIV).

Your blood sugar level may either rise or fall if you take:

Beta-blockers (used to treat high blood pressure), clonidine (used to treat high blood pressure), lithium salts (used to treat psychiatric disorders). Pentamidine (used to treat some infections caused by parasites) may cause hypoglycaemia which may sometimes be followed by hyperglycaemia. Beta-blockers like other sympatholytic medicines (such as clonidine, guanethidine, and reserpine) may weaken or suppress entirely the first warning symptoms which help you to recognise a hypoglycaemia.

4) How to use BASALOG[®]

General instructions

- Follow the instructions given by your healthcare provider (doctor, nurse, or pharmacist) about the type or types of insulin you are using. Do not make any changes with your insulin unless you have talked to your healthcare

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provider. Your insulin needs may change because of illness, stress, other medicines, or changes in diet or activity level. Talk to your healthcare provider about how to adjust your insulin dose.

- You may take BASALOG[®] at any time during the day but you must take it at the same time every day.
- Only use BASALOG[®] that is clear and colourless. If your BASALOG[®] is cloudy or slightly coloured, return it to your pharmacy for a replacement.
- Follow your healthcare provider's instructions for testing your blood sugar.
- Inject BASALOG[®] under your skin (subcutaneously) in your upper arm, abdomen (stomach area), or thigh (upper leg). Never inject it into a vein or muscle.
- Change (rotate) injection sites within the same body area

Use in Children

BASALOG[®] can be used in adolescents and children of 2 years and above. There are limited reports with the use of Insulin glargine in children less than 2 years old. Therefore, BASALOG[®] should only be used in children below this age under careful medical supervision.

Frequency of administration

You need one injection of BASALOG[®] every day, at the same time of the day. In children, only evening injection has been reported.

Method of administration

BASALOG[®] is injected under the skin. Do not inject BASALOG[®] in a vein, since this will change its action and may cause hypoglycaemia. Your doctor will show you in which area of the skin you should inject BASALOG[®]. With each injection, change

the puncture site within the particular area of skin that you are using

How to use Vial

Look at the vial before you use it. Only use it if the solution is clear, colourless and waterlike, and has no visible particles in it. Do not shake or mix it before use. Make sure that neither alcohol nor other disinfectants or other substances contaminate the insulin. Do not mix BASALOG[®] with any other insulins or medicines. Do not dilute it. Mixing or diluting may change the action of BASALOG[®]. Always use a new vial if you notice that your blood sugar control is unexpectedly getting worse. This is because the insulin may have lost some of its effectiveness. If you think you may have a problem with BASALOG[®], have it checked by your doctor or pharmacist. Inject the insulin under the skin. Use the injection technique advised by your doctor or diabetes nurse. Keep the needle under your skin for at least 10 seconds to make sure that the full dose has been delivered.

BASALOG[®] with any other insulins or medicines. Do not dilute it. Mixing or diluting may change the action of BASALOG[®].

Inject the insulin:

- Inject the insulin under the skin. Use the injection technique advised by your doctor or diabetes nurse.
- Keep the needle under your skin for at least 10 seconds to make sure that the full dose has been delivered.

If you have injected too much BASALOG[®]

Your blood sugar level may become too low (hypoglycaemia). Check your blood sugar frequently. In general, to prevent hypoglycaemia you must eat more food and monitor your blood sugar. For information on the treatment of hypoglycaemia.

If you forget to use it

If you have missed a dose of BASALOG[®] or if you have not injected enough insulin, your blood sugar level may become too High (hyperglycaemia). Check your blood sugar frequently. Do not take a double dose to make up for a forgotten dose.

If you stop using

This could lead to severe hyperglycaemia (very high blood sugar) and ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar).

Do not stop BASALOG[®] without speaking to a doctor, who will tell you what needs to be done. If you have any further questions on the use of this product, ask your doctor or pharmacist.

Insulin Mix-up

You must always check the insulin label before each injection to avoid medication mix-ups between BASALOG[®] and other insulins.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

5) While you are using BASALOG[®]

Things you must do

- If you have Medical conditions: medical conditions can alter your insulin requirements. Consult your doctor for a change in dose.

Things you must not do

- Driving and using machines: your ability to concentrate and react may be reduced if you have hypoglycaemia (low blood sugar). You should contact your doctor about the advisability of driving if you have:
- Frequent episodes of hypoglycaemia.
- Reduced or absent warning signs of hypoglycaemia.

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Things you must be careful of

- If you are drinking alcohol: watch for signs of a hypoglycaemia and never drink alcohol on an empty stomach.
- If you are exercising more than usual or if you want to change your usual diet.
- If you are going abroad: travelling over time zones may affect your insulin needs and the timing of your injections.
- If you are pregnant or plan to become pregnant. It is not known if BASALOG® may harm your unborn baby. It is very important to maintain control of your blood sugar levels during pregnancy. Your healthcare provider will decide which insulin is best for you during your pregnancy.
- If you are breast-feeding or plan to breast-feed. It is not known whether BASALOG® passes into your milk. Many medicines, including insulin, pass into human milk, and could affect your baby. Talk to your healthcare provider about the best way to feed your baby.

If you get a hypoglycaemic attack (Hypoglycaemia means your blood sugar level is too low)

The warning signs of a hypoglycaemic attack may come on suddenly and can include: cold sweat, cool pale skin; headache; rapid heartbeat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty in concentrating.

If you get any of these signs, eat glucose tablets or a high sugar snack (sweets, biscuits, fruit juice), then rest.

Don't take any insulin if you feel a hypoglycaemic attack coming on. Carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

Tell your relatives, friends and close colleagues that if you pass out (become unconscious), they must: turn you on your side and seek medical advice straight away. They must not give you any food or drink as it could choke you.

- **If severe hypoglycaemia** is not treated, it can cause brain damage (temporary or permanent) and even death.
- **If you have a hypoglycaemic attack** that makes you pass out, or a lot of hypoglycaemic attack, talk to your doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

Using glucagon

You may recover more quickly from unconsciousness with an injection of the hormone glucagon by someone who knows how to use it. If you are given glucagon you will need glucose or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital. Seek medical advice after an injection of glucagon; you need to find the reason for your hypoglycaemic attack to avoid getting more.

Causes of a hypoglycaemic attack

You get a hypoglycaemic attack if your blood sugar gets too low. This might happen:

- If you take too much insulin
- If you eat too little or miss a meal
- If you exercise more than usual.
- If you have an infection or illness (especially diarrhoea or vomiting)
- If you have a change in your need for insulin or

- If you have trouble with your kidneys or liver which gets worse.

If your blood sugar gets too high Your blood sugar may get too high (this is called hyperglycaemia).

The warning signs appear gradually. They include: increased urination; feeling thirsty; losing your appetite; feeling sick (nausea or vomiting); feeling drowsy or tired; flushed, dry skin; dry mouth and a fruity (acetone) smell of the breath.

If you get any of these signs, test your blood sugar level and test your urine for ketones if you can. Then seek medical advice straight away.

These may be signs of a very serious condition called diabetic ketoacidosis. If you don't treat it, this could lead to diabetic coma and death.

Causes of hyperglycaemia

- Having forgotten to take your insulin
- Repeatedly taking less insulin than you need
- An infection or a fever
- Eating more than usual
- Less exercise than usual.

6) Side effects

BASALOG® is known to cause some side effects.

- If you take more BASALOG® than your requirement it may cause hypoglycaemia (low blood sugar). See the advice in 5 (while you are using it).
- If you take less BASALOG® than your requirement it may cause hyperglycaemia (high blood sugar).

Common side effects

Symptoms resulting from release of adrenaline are common manifestations of mild to moderate hypoglycaemia. They include cold sweats, anxiety, shakiness, hunger, rapid heartbeat, headache, and nervousness. Weight gain is common

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when taking insulin.

Less common side effects

Allergic reactions and changes at the injection site (Lipodystrophy) may occur at the injection site as a consequence of failure to rotate injection sites within an area. If you inject yourself too often at the same site, fatty tissue under the skin at this site may shrink (lipoatrophy) or thicken (lipohypertrophy). Change the site with each injection may help to prevent such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor because these reactions can become more severe, or they may change the absorption of your insulin if you inject in such a site.

Signs of allergy

Reactions (redness, swelling, itching) at the injection site may occur (local allergic reactions). These usually disappear after a few weeks of taking your insulin. If they do not disappear, see your doctor

Seek medical advice immediately

- if signs of allergy spread to other parts of the body, or
- if you suddenly feel unwell and you start sweating; start being sick (vomiting); have difficulty in breathing; have a rapid heartbeat; feel dizzy; feel like fainting.
- You may have a very rare serious allergic reaction to BASALOG[®] or one of its ingredients (called a systemic allergic reaction). See also warning in 3 Before You Use BASALOG[®]
- Abnormal accumulation of fluid (oedema) may occur upon initiation of insulin therapy. These symptoms are usually of transitory nature

Eye reactions:

A marked change (improvement or worsening) in your blood sugar control can disturb your vision temporarily. If you have

proliferative retinopathy (an eye disease related to diabetes) severe hypoglycaemic attacks may cause temporary loss of vision.

Very rare reported side-effects (affects less than 1 user in 10 000). In very rare cases, dysgeusia (taste disorders) and myalgia (muscular pain) can occur.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website <http://portal.bpfk.gov.my/> (Consumers →Reporting)

7) Storage and Disposal of BASALOG[®]

Storage:

Keep out of the reach and sight of children. Do not use BASALOG[®] after the expiry date which is stated on the carton and on the label of the vial after “EXP”. The expiry date refers to the last day of that month.

Unopened/In-use vials:

Store in a refrigerator at temperature between 2°C to 8°C. It should not be allowed to freeze.

Opened/In-use vials:

The solution can be kept at room temperature (up to 30°C) for up to 28 days once the vial has been put to use.

Do not expose to excessive heat or direct sunlight. Do not use it after this time period. It is recommended that the date of the first use be noted on the label. Do not use BASALOG[®] if you notice particles in it. Only use BASALOG[®] if the solution is clear, colourless and waterlike. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Disposal:

Any unused product or waste material should be disposed of in accordance with local requirements. Basalog formulations should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

8) Product Description

What it looks like

Clear, colourless solution.

Presentation

Vial – 10 mL per carton

Ingredients

Active Ingredients

Insulin glargine 100 IU/mL

Inactive Ingredients

Zinc Chloride, Glycerin, m-Cresol, Sodium Hydroxide, Hydrochloric Acid and Water for Injection.

MAL Number

MALXXXXXXXXXA

9) Manufacturer and Product Registration Holder

Biocon Sdn. Bhd. (930330-U)
No.1, Jalan Bioteknologi 1,
Kawasan Perindustrian SiLC,
79200 Iskandar Puteri, Johor, Malaysia.

10) Date of Revision

05th March 2019